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Supreme Court of the United States

OCTOBER TERM, 1965

ABBOTT LABORATORIES, ET AL., *Petitioners,*
v.
ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, *Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITIONERS' REPLY BRIEF

GERHARD A. GESELL
701 Union Trust Building
Washington 5, D.C.
Attorney for Petitioners

Of Counsel:

STANLEY L. TEMKO
HERBERT DYM
COVINGTON & BURLING
701 Union Trust Building
Washington 5, D.C.

HAYWARD H. COBURN
DRINKER BIDDLE & REATH
1100 Philadelphia National Bank Building
Broad and Chestnut Streets
Philadelphia 7, Pennsylvania
Attorney for Merck & Co., Inc.

LLOYD N. CUTLER
MARSHALL HORNBLOWER
WILMER, CUTLER & PICKERING
900 17th Street, N.W.
Washington 6, D.C.

C. JOSEPH STETLER
JOHN K. WORLEY
Pharmaceutical Manufacturers Association
1155 15th Street, N.W.
Washington 5, D.C.
Attorneys for Pharmaceutical Manufacturers Association

ALEXANDER L. NICHOLS
WILLIAM S. MEGONIGAL, JR.
MORRIS, NICHOLS, ARSHT & TUNNELL
3000 DuPont Building
Wilmington 1, Delaware
Attorneys for Petitioners

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The central question presented by this Petition has been narrowed as a result of the Solicitor General's concessions and at the same time he has presented this Court with additional reasons for granting the writ.

1.

The issue now is whether either the Administrative Procedure Act or the Declaratory Judgment Act are available to seek review of Food and Drug Administration regulations prior to an actual enforcement proceeding.

The Court of Appeals' surprising determination, to which the Solicitor General lends his support, that Congress intended to preclude review of regulations of the type at issue here because it specified in Section 701(f) of the Food and Drug Act the availability of another type of judicial review for certain regulations is patently unsound. Even as

to regulations made reviewable under that section, the judicial review provisions of the Act are stated to be nonexclusive.[1] A fortiori, Congress did not intend the judicial review provisions of Section 701(f) to operate to preclude review under the Administrative Procedure Act or the Declaratory Judgment Act of regulations not covered by that section. Indeed, the legislative history of the Act makes it clear that Congress, in enacting the Food and Drug Act in 1938, intended only to provide an additional, nonexclusive method of obtaining review of certain regulations, and did not intend to preclude review under the Declaratory Judgment Act or general equity jurisdiction of any FDA regulation. As stated in the House Report on the 1938 legislation:

> "There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.
>
> "The special type of review above outlined, where the proceedings are instituted by the individual or business organization affected, will permit an early determination of the validity of the Secretary's action with respect to any proposal for a regulation, amendment, or repeal, and make for prompt certainty as to legal rights." H. R. Rep. No. 2139, 75th Cong., 3d Sess. 11 (1938).

Even absent this decisive legislative history, the Administrative Procedure Act, enacted in 1946, would nevertheless be available to challenge the regulations at issue here. This Court has required "clear and convincing evidence"

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[1] Section 701(f)(6) of the Act states that "the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

of congressional intent to withhold review under the APA, *Rusk* v. *Cort*, 369 U. S. 367, 379-80 (1962), and has quoted with approval the statement in the House Report on the APA that "the mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review." *Heikkila* v. *Barber*, 345 U. S. 229, 232 (1953). In addition, the decision of the Court of Appeals on this point is inconsistent with the recent decision of the District of Columbia Circuit in *Elmo Division of Drive-X Co.* v. *Dixon*, 348 F. 2d 342, 343 (D. C. Cir. 1965), where that Court held with respect to the FTC that "statutory provisions concerning review of agency action by the Courts of Appeals do not in and of themselves . . . preclude District Court jurisdiction."

The question whether Congress precluded review of FDA regulations like those here involved should be decided by this Court. This issue is presented in every case where FDA regulations are challenged in declaratory judgment actions, including a case now pending in the Second Circuit. *Toilet Goods Ass'n* v. *Celebrezze*, 235 F. Supp. 648 (S. D. N. Y. 1964), on appeal, 2d Cir., No. 30261.

The issue, moreover, has far broader ramifications. The effect of the decision below would be that neither the Administrative Procedure Act nor the Declaratory Judgment Act would ever be available to review any order of any administrative agency where the agency's governing statute specifically authorizes the review of certain other orders. This proposition, on its face, is erroneous. In *Leedom* v. *Kyne*, 358 U. S. 184 (1958), for example, this Court held that the fact that certain types of NLRB orders were made reviewable in the Courts of Appeals did not by negative implication preclude equitable actions in a District Court to review other types of NLRB orders. Compare *United Gas Pipeline Co.* v. *FPC*, 181 F.2d 796 (D. C. Cir.), *cert. denied*, 340 U. S. 827 (1950), and *Arrow Airways, Inc.* v. *CAB*, 182 F. 2d 705 (D. C. Cir.), *cert. denied*, 340 U. S.

828 (1950), where the Court of Appeals held in each instance that orders of an administrative agency not reviewable in the Courts of Appeals under the judicial review provision applicable to the agency may be challenged in the District Courts under their general equity jurisdiction.

2.

The Solicitor General's concession (Br. Opp. 4) that "there may be substance to petitioners' contention" that the decision below is inconsistent with *Frozen Food Express* v. *United States,* 351 U. S. 40 (1956), should not be permitted to eliminate that issue from this case. While the Solicitor General concedes (Br. Opp. 7) that *Frozen Food Express* held that an "interpretive order"[2] can be challenged in advance of an enforcement proceeding, the fact of the matter is that the Government has in this and other litigation in the lower courts sought vigorously to narrow this decision to a point where it really will have no meaning. Respondents contended below that *Frozen Food Express* is applicable only where orders of the agency involved are made reviewable by specific statutory provisions dealing solely with that agency and asserted that this Court in *Frozen Food Express* did not contemplate review of interpretive orders under the Declaratory Judgment Act or the Administrative Procedure Act. This, it is submitted, flies in the face of the true meaning of the decision, and if certiorari is not granted here, the lower courts will still be open to arguments by respondents giving this decision a far too narrow effect.

The situation may be most graphically illustrated by the fact that respondents are relying on the Court of Appeals' decision in this very case to reinforce in other litigation this narrow and inappropriate view of justiciability, so plainly

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[2]The present order goes far beyond being "interpretive." It nowhere states that it purports to be merely the Secretary's "interpretation" of the statute. It *commands* petitioners to label their drugs in a particular way and states that a failure to do so would cause the drugs to be mislabeled.

inconsistent with *Frozen Food Express.* In a case now pending in the Second Circuit, *Toilet Goods Ass'n* v. *Celebrezze,* No. 30261, respondents are arguing—in contrast to the Solicitor General's concession as to the holding of *Frozen Food Express*—that "interpretive" regulations can never be challenged when they are promulgated and they cite for this proposition the Court of Appeals' decision below. (The Government's discussion in its brief before the Second Circuit in the *Toilet Goods Ass'n* case of the Court of Appeals' decision in this case is reprinted in the Appendix hereto.)[3]

In sum, we have a situation where the Solicitor General acknowledges that the Court of Appeals' holding on justiciability appears to be inconsistent with a decision of this Court, but where the Department of Justice continues in the lower courts to rely upon this erroneous holding. The decision of the Court of Appeals, contrary to this Court's decision in *Frozen Food Express,* that no justiciable controversy was presented should not be permitted to stand as an obstacle to obtaining prompt judicial determinations as to the validity of administrative regulations in this and other cases.

3.

Respondents strain to minimize the hardship to petitioners of having to act at their peril and await an enforcement proceeding before it can be determined whether the regulations are valid.[4] And, as if fear of criminal prosecu-

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[3]It will be noted that the respondents' brief in the *Toilet Goods Ass'n* case cites in support of their position an article by Professor Davis. Professor Davis, however, has specifically approved the District Court's holding in that case that other regulations issued by the respondents can be challenged in a declaratory judgment action. 3 Davis, *Administrative Law* § 21.08, at 45 (Supp. 1965).

[4]Respondents also mention the provision in Section 502(e)(1)(B) for exemptions from the requirements of that section where compliance would be "impracticable". This provision, however, con-

tion were the only basis for this action, the Solicitor General now represents (Br. Opp. 5-6) that criminal prosecutions will not be brought under the regulations until their validity has been authoritatively determined.

Even on the assumption that the Government may be barred from bringing criminal proceedings by statements in a brief, it was admitted below that the regulations would be enforced. The regulations can still be enforced through seizure proceedings and injunction actions, and, in addition, respondents can attempt to enforce the regulations by preventing the initial marketing of drugs and antibiotics whose printed matter does not comply with the regulations. It is no "minimal hardship" (Br. Opp. 8) to subject individual petitioners to months of delay in securing approvals to market new and valuable drugs in order to obtain a judicial determination as to the validity of the regulations. Nor is it a "minimal hardship" to individual petitioners that their drugs be seized and kept off the market for failure to comply with the regulations. Seizure is a drastic sanction carrying opprobrium comparable to a criminal prosecution.

This Court has established that it is not necessary that there be a criminal sanction in order for administrative regulations to be reviewed. Thus, in both *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942), and *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956), regulations of the FCC were held to be reviewable even though the regulations at issue there were enforced only by administrative action; there was no provision for the institution of judicial proceedings to prosecute violators of the regulations. Here, too, even absent the

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templates exemptions in individual situations, not where an entire industry challenges the legality of the "every time" requirement imposed by the respondents. In any event, the exemption provision applies only to one section of the regulations, that dealing with labeling, and does not apply to the section dealing with advertising, the legality of which was also challenged in this action (R. 14a, 66a; Pet. App. 3a).

possibility of criminal prosecution, petitioners are entitled to a determination of the regulations' validity in this declaratory judgment action in light of the other drastic sanctions available to the Government. In any event, it is quite clear that the Solicitor General's representation attempting to remove the threat of criminal prosecution at this stage of the proceeding—more than two years after the complaint was filed—cannot destroy the jurisdiction that the District Court had when the action was instituted. See *American Life Ins. Co.* v. *Stewart*, 300 U. S. 203, 215 (1937); *Spector Motor Service, Inc.* v. *O'Connor*, 340 U. S. 602, 605 (1951).

Petitioners should not be forced to the choice of either complying with regulations believed to be unlawful[5] or running the risk of suffering severe sanctions. Respondents should not be permitted to hold an entire industry at hazard, arbitrarily selecting both the companies against which these sanctions will be invoked and the drugs whose marketing will be delayed even if the regulations are ultimately held to be unlawful. There is simply no reason for not having, once and for all, a final determination in this declaratory judgment action of the validity of the regulations, an issue that was tendered below on cross motions for summary

[5]Since, as respondents acknowledge (Br. Opp. 6) "the underlying merits of the controversy are not presently before the Court," petitioners do not intend to show here why the regulations are invalid. It is sufficient to note the District Court's holding that the regulations are inconsistent with the statute and not supported by the legislative history of the 1962 Drug Amendments. (R. 54a-58a).

It should be emphasized, moreover, contrary to respondents' assertion (Br. Opp. 7), that petitioners did *not* urge that the regulations are invalid because they rendered printed material "confusing and repetitious . . . and difficult . . . to read." They alleged that the regulations were invalid because they were not authorized by the statute. The allegation quoted by respondents, which was never controverted, was among those directed to the injury that compliance with the regulations would cause petitioners. (R. 13a).

judgment presenting no disputed factual issues. No fact bearing on the respondents' power to issue the regulations will be any different in a later enforcement proceeding from what it is today.

The petition for a writ of certiorari should be granted.

Respectfully submitted,

GERHARD A. GESELL
701 Union Trust Building
Washington 5, D.C.
Attorney for Petitioners

Of Counsel:

STANLEY L. TEMKO
HERBERT DYM
COVINGTON & BURLING
701 Union Trust Building
Washington 5, D.C.

HAYWARD H. COBURN
DRINKER BIDDLE & REATH
1100 Philadelphia National Bank Building
Broad and Chestnut Streets
Philadelphia 7, Pennsylvania
Attorney for Merck & Co., Inc.

LLOYD N. CUTLER
MARSHALL HORNBLOWER
WILMER, CUTLER & PICKERING
900 17th Street, N.W.
Washington 6, D.C.

C. JOSEPH STETLER
JOHN K. WORLEY
Pharmaceutical Manufacturers Association
1155 15th Street, N.W.
Washington 5, D.C.
Attorneys for Pharmaceutical Manufacturers Association

ALEXANDER L. NICHOLS
WILLIAM S. MEGONIGAL, JR.
MORRIS, NICHOLS, ARSHT & TUNNELL
3000 DuPont Building
Wilmington 1, Delaware
Attorneys for Petitioners

APPENDIX

Brief Filed by the United States Attorney for the Southern District of New York, February 9, 1966, in *The Toilet Goods Ass'n, Inc., et al. v. Anthony J. Celebrezze, et al.*, United States Court of Appeals for the Second Circuit, Docket No. 30261, September Term, 1965.

"The significance of this distinction [between legislative and interpretative regulations] is accentuated by the recent decision of the Third Circuit in *Abbott Laboratories* v. *Celebrezze,* 352 F. 2d 286 (3rd Cir. 1965), a case strikingly similar to this dispute. There, as here, FDA issued certain regulations expressing its interpretation of new amendments to the Act. There, as here, the affected industry made no effort at compliance. There, as here, there was no effort by the Government to enforce the regulations. There, as here, the industry banded together to mount a massive assault on the regulations. There, as here, they sought a declaratory judgment and injunction. There, as here, they contended that appellants had plainly exceeded their statutory authority.

"The District Court in *Abbott* refused to dismiss the complaint and granted summary judgment voiding the regulations [228 F. Supp. 855 (D. Del. 1964)]. The District Court in this case relied heavily on that decision in its initial opinion (94a). However, the Court of Appeals reversed *Abbott* and dismissed the complaint for lack of a justiciable controversy. It recognized the patently interpretative nature of the regulations and the Congressional policy limiting prior judicial review of actions under the Food, Drug and Cosmetic Act. It found that the regulations in question did not have the force and effect of law; that they were not an 'adjudication,' 'order,' or 'licensing' under Section 2(d) of the Administrative Procedure Act [5 U. S. C. § 1001(d)] and, therefore, that they were not reviewable by declaratory judgment.

"The rationale of *Abbott Laboratories* applies with equal vigor to this case. The District Court here sought to distinguish *Abbott Laboratories* on the grounds that the regulation there at issue were [sic] interpretive as opposed to legislative (12a).* At the same time the District Court criticized such distinctions as 'hypertechnical' (9a). A plain reading of the statute discloses that FDA cannot issue 'legislative' regulations defining the scope of its regulatory authority. A plain reading of the regulations discloses that they are labelled as interpretative and fall within this classification by their very language. As such, they are not reviewable by declaratory judgment."

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*For a thorough discussion of the theoretical distinction between interpretative and legislative regulations see Davis, Administrative Rules—Interpretative, Legislative, & Retroactive, 57 Yale L. J. 919, 928-929 (1948).